

REMARKS

A. BACKGROUND

The present Amendment is in response to the Office Action mailed June 1, 2009. Claims 36 and 38-57 were pending and rejected in view of cited art.¹ Claim 36 is amended, claims 50-57 are cancelled and claim 73-78 have been added. Claims 36, 38-49, and 73-78 are now pending in view of the above amendments.²

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, are consistent with the Examiner's understanding.

B. PRIOR ART REJECTIONS

I. REJECTION UNDER 35 U.S.C. § 103

The Office Action rejected claims 36, 38-40, 44, and 48 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Reissue Patent No. RE36,974 (*Bonutti*) in view of U.S. Patent No. 5,810,884 (*Kim*).

The Office Action at page 2 admits, "Bonutti discloses a delivery sheath in which the filament and bar are disposed but fails to disclose a sharpened tip at the distal end." The Office Action at page 2 then asserts, "However, Kim teaches that it is well known in the art to include a sharpened tip (48) on the distal end of a delivery device. The sharpened tip is tapered which facilitates its insertion into tissue and is advantageous because the same instrument can be used to both form the channel to the surgical site and deliver the sealing instrument to that site." In

¹ Although the prior art status of the cited art is not being challenged at this time, Applicant reserves the right to challenge the prior art status of the cited art at any appropriate time, should the need arise. Accordingly, any arguments and amendments made herein should not be construed as acquiescing to any prior art status of the cited art.

support of the Office Action's assertion that *Kim* and *Bonutti* are properly combined, the Office Action at page 2 further states, "It would have been well within the purview of one skilled in the art to use such a sharpened tip on the delivery sheath of *Bonutti* as taught by *Kim* because one skilled in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." Applicant respectfully disagrees.

Regardless of the rationale used as the basis for an obviousness rejection, the Office Action must determine the scope and content of the prior art. (*See* MPEP §2141(I)(A)). While it may be clear that one skilled in the art has good reason to pursue *known* options, such a situation is not the case in the present application. In particular, if a reference teaches away from the use of an element in a given manner, the use of that element in that manner is not known. In such a case, it would not be obvious for one skilled in the art to try to use an element in a manner contrary to that taught by the prior art.

With regard to claim 36, Applicant respectfully submits that *Bonutti* teaches away from the use of the element the Office Action proposes to combine with the teachings of *Kim*. More specifically, *Bonutti* at column 8, lines 37-41 appears to contemplate the use of the suture anchor for soft tissue: "In joining soft tissue to soft tissue, it is preferable to insert the anchor directly through the soft tissue, *not into an opening in the tissue*. Thus, the anchor may have a slightly sharpened or pointed distal end (tip) to push through the tissue layers." (Emphasis added). There would, therefore, be no reason to combine the sharpened tip of *Kim* with the device of *Bonutti* and any combination would appear to change the principle of operation of *Bonutti* by eliminating the need for the "sharpened or pointed distal (tip)" of the anchor and changing the "inserter guide flange portion 94" or the "tapered distal end portion 212" to a sharpened tip. (*See also* MPEP 2413.01). Since *Bonutti* teaches away from an apparatus that includes "a delivery sheath having proximal and distal ends, a lumen extending therebetween to contain the bar and filament, and a sharpened tip at the distal end," as recited by claim 36, Applicant respectfully requests that the rejection under 35 U.S.C. § 103(a) be reconsidered and withdrawn. Claims 38-40, 44, and 48 depend from claim 36 and are therefore patentable over *Bonutti* and *Kim* for at least the same reasons.

² Support for the claim amendments and/or new claim(s) can be found throughout the specification and/or drawings as originally filed.

Claims 41-43 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Bonutti* in view of *Kim* as applied to claim 36 and further in view of U.S. Patent No. 5,411,520 (*Nash*). Claims 45-47 and 49 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Bonutti* in view of *Kim* as applied to claim 36 and further in view of U.S. Patent No. 6,506,197 (*Rollero*). As previously discussed, the combination of *Kim* and *Bonutti* fails to teach or suggest "a delivery sheath having proximal and distal ends, a lumen extending therebetween to contain the bar and filament, and a sharpened tip at the distal end" as recited by claim 36, because *Bonutti* teaches away from the proposed combination. Neither *Nash*, cited by page 3 of the Office Action as disclosing "that it is well known in the art to include a tensioning device" nor *Rollero*, which page 5 of the Office Action cited as disclosing "that it is old and well known in the art to include a plurality of attachment points," remedies the deficiencies of *Kim* and *Bonutti*. Therefore, Applicant respectfully submits that independent claim 36 and associated dependent claims 41-43, 45-47, and 49 are neither taught nor suggest by *Bonutti*, *Kim*, *Nash*, or *Rollero*, whether alone or in combination.

Claims 50, 51, and 54-57 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,228,096 (*Marchand*). Claims 52 and 53 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Marchand* in view of *Kim* as applied to claim 50 and further in view of *Rollero*. In view of the cancellation of claims 50-57, Applicant respectfully submits the rejections are moot.

Independent claim 73 recites an apparatus that includes "a bar having proximal and distal ends and a first bore extending laterally therethrough, the bar having a distal end having a generally *planar surface oriented parallel to the bore*" as well as "a delivery sheath having proximal and distal ends, a lumen extending therebetween to contain the bar and filament, and a *sharpened tip* at the distal end" and therefore further distinguishes over the current prior art of record.

Independent claim 76 recites "an elongate bar having a proximal end, a distal end, a first bore extending laterally therethrough, and a *second bore extending longitudinally from the proximal end to the distal end*" and therefore distinguishes over the current prior art of record.

C. CONCLUSION

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 1st day of October, 2009.

Respectfully submitted,

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